

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

APOTEX, INC.,

Plaintiff,

v.

CEPHALON, INC., et al.,

Defendants.

Case No. 06-cv-02768-MSG

**DEFENDANT CEPHALON INC.'S MEMORANDUM IN OPPOSITION TO
PLAINTIFF APOTEX, INC.'S THIRD DAUBERT MOTION**

(Redacted Version)

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Pursuant to Federal Rule of Evidence 702 and the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), Cephalon opposes Apotex's third *Daubert* motion, which seeks to exclude the expert reports and testimony of Drs. Lynn Van Campen, David Bugay, Markus Antonietti, and Robert Williams (collectively "Cephalon's infringement experts") related to data, information, or testing conducted on Apotex's modafinil tablets.

INTRODUCTION

Apotex failed to produce samples in its possession of Canadian modafinil products [REDACTED]
[REDACTED]
[REDACTED] Cephalon, [REDACTED]
[REDACTED] independently acquired samples of these tablets, tested them, and produced the results to Apotex within days after the tests were conducted. Apotex never came forward with any of its own tests on its own Canadian products, [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] Apotex is trying to preclude that evidence based on speculation and a serious misreading of the *Daubert* decision and its progeny. Apotex's motion should be denied.

To be admissible, expert testimony must be by a qualified expert, must be "based upon sufficient facts or data," and must be "the product of reliable principles and methods," which the expert must have "applied . . . reliably to the facts of the case." Fed. R. Evid. 702. The expert testimony at issue on this motion satisfies this standard and thus should not be excluded. As a threshold matter, Cephalon's infringement experts are clearly qualified to offer opinions and testimony on Cephalon's testing of Apotex's modafinil tablets and the results of that testing. Apotex does not even try to argue to the contrary. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Apotex makes no serious challenge to the scientific validity of the tests that Cephalon's experts performed on Apotex's modafinil tablets. Apotex mentions, in a footnote, that the method Dr. Van Campen used to isolate modafinil active pharmaceutical ingredient ("API") from Apotex's tablets has not been published in a peer-reviewed publication. But as shown below, neither *Daubert*, *Kumho Tire*, nor any subsequent Third Circuit authority holds that publication (peer-reviewed or otherwise) is a litmus test for scientific reliability or admissibility.

Apotex instead argues that the tests conducted by Cephalon's infringement experts are unreliable because the origins and storage conditions of the tested tablets are unknown to Apotex. However, Apotex's counsel was provided identifying information regarding the tablets—including markings on the bottle label indicating DIN 02285398, batch JL0614, expiration January 2012—by Cephalon's counsel on November 11, 2010. (Exhibit ("Ex.") 1, Letter from G. Teran to B. Sodikoff, Nov. 11, 2010.)¹ Cephalon's counsel demanded to know whether Apotex disputed that this was an Apotex-manufactured lot, or had a Rule 11 basis to assert that the tablets were not genuine. (*Id.*) Apotex never raised any such dispute. Dr. Van

¹ Unless otherwise noted, all exhibits referenced herein are attached to the Declaration of Omar A. Khan In Support of Defendant Cephalon, Inc.'s Memorandum in Opposition to Plaintiff Apotex, Inc.'s Third *Daubert* Motion.

Campen reported that the tablets were in a factory-sealed bottle that was in good condition. Photographs were taken of the bottle and produced to Apotex. Apotex never challenged these observations or disputed the authenticity of the photographs; indeed, it never even asked to inspect the bottle or the tablets.

Apotex also complains that the results of Cephalon's tablet tests were disclosed in an untimely manner. Cephalon's motion to compel samples from Apotex was denied on April 9, 2010. (D.I. No. 232.) Cephalon deposed Apotex's fact witnesses in July and August of 2010.

[REDACTED]

[REDACTED] Cephalon acquired the Canadian tablets in August 2010, imported them in October 2010, tested them immediately, and produced the results on October 25, 2010, as soon as the testing was completed.

None of Apotex's arguments provides an adequate basis for excluding the opinions and testimony of Cephalon's infringement experts related to data, information, or testing of Apotex's modafinil tablets. Accordingly, the motion should be denied.

ARGUMENT

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

B. The Tablet Separation Method Performed by Dr. Van Campen Is Scientifically Valid

Apotex alleges (in passing) that the tablet separation method used by Dr. Van Campen to isolate modafinil API from Apotex's tablets is not reliable because it has not been published in a peer-reviewed journal and has not been used outside of the litigation context. (Apotex's Third *Daubert* Mot. at 7 n.6.) However, the Supreme Court explicitly stated in *Daubert* that "[p]ublication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability, and in some instances well-grounded but innovative theories will not have been published. 509 U.S. at 593 (citations omitted). The Supreme Court and the Third Circuit have rejected the notion that publication in a peer-reviewed journal is a litmus test for admissibility. See *United States v. Mitchell*, 365 F.3d 215, 235 (3d Cir. 2004) (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 n.8 (3d Cir. 1994)) (listing peer review of an expert's method as only one of eight different factors courts examine in determining whether testimony meets the reliability requirement of *Daubert*); *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806-07 (3d Cir. 1997) (noting that the eight factors set forth in *Paoli* "are neither exhaustive nor applicable in every case").

As Dr. Antonietti explained in his deposition, the techniques used by Dr. Van Campen to isolate modafinil API from Apotex's tablets are "well-established procedures," which he himself has used to isolate API from a solid dosage form. (Ex. 2, Antonietti Dep. Tr. 136:1-137:23; *see* Ex. 3, Antonietti Rebuttal Rep't ¶¶ 40-41.) Dr. Williams also stated that the tablet separation protocol employs a technique that "was developed in the 1950s and is widely used in a number of disciplines." (Ex. 4, Williams Rebuttal Rep't at 8 n.3.) Far from being unreliable, Dr. Van Campen's protocol applied basic, well known, routine laboratory techniques to the problem of tablet separation to successfully isolate modafinil API from Apotex's tablets. Apotex has offered no countervailing evidence to refute the testimony and opinions of Cephalon's experts regarding the reliability of Dr. Van Campen's protocol.

C. The Origin and Chain of Custody of Apotex's Tablets Tested by Cephalon's Experts Is Documented

The tablets that Dr. Van Campen and Dr. Bugay tested were acquired in Canada in early August 2010, lawfully imported to the United States in October, and tested immediately thereafter.² Cephalon has produced photographs of the bottle of Apo-Modafinil tablets as it arrived and was opened at Zeeh Station. (Ex. 5, Van Campen Report, Ex. D.) Cephalon has

²



even produced video of the bottle being opened at Dr. Van Campen's laboratory. (Ex. 6, Van Campen Video.) The tablets were in a factory sealed bottle bearing Apotex's imprint and a lot number – JL0614. Cephalon's counsel asked Apotex's counsel whether Apotex denied manufacturing this lot; Apotex never made any such denial. (Ex. 1, Letter from G. Teran to B. Sodikoff, Nov. 11, 2010.) Notably, Apotex has never asked even to inspect the bottle, nor has it raised any claim that the bottle was not genuine or was tampered with.

Instead, Apotex asserts that Cephalon's infringement experts do not know when and how the tested tablets were imported into the United States, nor how long and under what conditions the tablets were stored before they arrived at Dr. Van Campen's laboratory. (Apotex's Third *Daubert* Mot. at 7.) The identity and integrity of the Apo-Modafinil tablets tested by Drs. Van Campen and Bugay are well established by the affidavits attached to this opposition. There is no reasonable dispute that when the tablets arrived in Dr. Van Campen's laboratory, the bottle was still factory-sealed and in good condition.³

Apotex knows that these tablets are genuine, and instead resorts to speculation that maybe, perhaps, temperature fluctuations could have somehow altered the particle size. Apotex does not cite a shred of evidence for this proposition, because it cannot. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

³ See Ex. 17, Perron Declaration ¶¶ 5, 7; Ex. 18, Zakaib Declaration ¶¶ 2-3; Ex. 19, Daley Declaration ¶¶ 2, 7; Ex. 20, Swites Declaration ¶¶ 2, 13. At no time was the bottle tampered with in any way.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

D. Cephalon Was Timely in Producing Tablet Testing Results to Apotex

Apotex complains that Cephalon did not disclose the results of tablet testing prior to the close of fact discovery or the *Markman* hearing. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Apotex cannot possibly claim prejudice concerning testing on its own products. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Apotex knew this in February 2010, when Cephalon requested samples of Apotex's products for purposes of testing in this litigation. Apotex knew this in March 2010, when it wrongly claimed that it did not possess relevant samples and that Cephalon was asking for products that did not exist. (Cephalon *Daubert* Mot., Ex. 3, Apotex Opp. to Cephalon Mot. to Compel Samples at 2-3.) [REDACTED]

[REDACTED]

⁴ Some data from Apotex's Canadian ANDS is redacted under the terms of Canada's Access to Information Act. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Cephalon obtained Apotex's Canadian tablets as described above, and conducted particle size testing. On October 25, 2010, immediately after completing the data analysis of the particle size tests on which Cephalon's infringement experts rely in their reports, Cephalon served Apotex with Supplemental Infringement Contentions disclosing the tablet test results, and produced documents showing the methods used and the data obtained. On Friday, November 5, 2010, Apotex requested additional underlying data, which Cephalon produced as soon as the requested data could be obtained from the respective experts—on November 8-11, 2010.⁵ (Ex. 14, Email from B. Sodikoff to G. Teran, Nov. 5, 2010; *id.*, Email from G. Teran to B. Sodikoff,

⁵ In its motion, Apotex mischaracterizes Cephalon's later productions, suggesting that Cephalon continued to produce tablet testing data until December 9, 2010. (Apotex's Third *Daubert* Mot. at 5.) The productions after November 11, 2010 contained documents relied on by Cephalon's validity experts, along with the results of particle size studies performed on material other than Apotex's modafinil tablets. Cephalon's infringement experts relied on these later-produced studies in their reply reports to rebut criticisms of the tablet testing protocols raised by Apotex's experts in their rebuttal reports.

Nov. 8, 2010; Ex. 15, Email from G. Teran to B. Sodikoff, Nov. 10, 2010; Ex. 14, Email from Yvon to Sodikoff, Nov. 11, 2010.)

Although Apotex's experts were aware of the additional data produced by Cephalon and purported to reserve the right to supplement or amend their opinions after considering that data, at no time between the November 8-11, 2010 productions and the present has Apotex sought to supplement its expert reports. (Cephalon *Daubert* Mot, Ex. 8, Beach Rebuttal Rep. ¶ 4; Ex. 16, Asher Rebuttal Rep. at 7-8 n.2, ¶ 31.) Moreover, Apotex's experts had ample time to consider all of the tablet testing data prior to Apotex's deposition of the first of Cephalon's infringement experts, Dr. Van Campen, on December 29, 2010.

CONCLUSION

For all of the foregoing reasons, Cephalon's evidence related to the data, information, and testing conducted on Apotex's modafinil tablets meets the standards of admissibility set by Federal Rule of Evidence 702 and *Daubert*. Therefore, the Court should deny Apotex's motion to exclude the expert reports and testimony of Drs. Van Campen, Bugay, Antonietti, and Williams.

Dated: February 25, 2011

Respectfully submitted,

/s/ Robert J. Gunther, Jr.

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CERTIFICATE OF SERVICE

I certify that on the date set forth below Defendant Cephalon, Inc.'s Memorandum in Opposition to Plaintiff Apotex, Inc.'s Third *Daubert* Motion (redacted version), and the Declaration of Omar A. Khan In Support of Defendant Cephalon, Inc.'s Memorandum in Opposition to Plaintiff Apotex, Inc.'s Third *Daubert* Motion (redacted version) were electronically filed pursuant to the Court's CM/ECF system, and that those documents are available for downloading and viewing from the CM/ECF system. Notice of this filing will be sent to all counsel of record by operation of the CM/ECF system.

Date: February 25, 2011

/s/ Robert J. Gunther, Jr.